DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 19, 2015

Merit Medical Systems, Inc.
Michaela Rivkowich
Principal Regulatory Affairs Specialist
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K150257
Trade/Device Name: PreludeEASE Hydrophilic Sheath Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: May 21, 2015
Received: May 22, 2015

Dear Ms. Rivkowich:

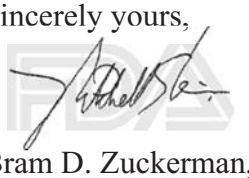
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
PreludeEASE Hydrophilic Sheath Introducer

Indications for Use *(Describe)*
The Merit PreludeEASE Hydrophilic Sheath Introducer is intended to provide access and facilitate the percutaneous introduction of various devices into veins and/or arteries, including but not limited to the radial artery, while maintaining hemostasis for a variety of diagnostic and therapeutic procedures.

The access needle with inner metal needle and outer plastic cannula is used to gain access to the vein or artery for placement of guide wires.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5.0 510(k) Summary

General Provisions	Submitter Name:	Merit Medical Systems, Inc.
	Address:	1600 West Merit Parkway South Jordan, UT 84095
	Telephone Number:	(801) 208-4196
	Fax Number:	(801) 253-6932
	Contact Person:	Michaela Rivkowich
	Date of Preparation:	February 2, 2015
	Registration Number:	1721504
Subject Device	Trade Name:	PreludeEASE™ Hydrophilic Sheath Introducer
	Common/Usual Name:	Sheath Introducer
	Classification Name:	Catheter Introducer
	Regulatory Class:	II
	Product Code:	DYB
	21 CFR §:	870.1340
	Review Panel:	Cardiovascular
Predicate Device	Trade Name:	PreludeEASE™ Hydrophilic Sheath Introducer
	Classification Name:	Sheath Introducer
	Premarket Notification:	K140543
	Manufacturer:	Merit Medical Systems, Inc.
	This predicate has not been subject to a design-related recall.	
Reference Device	Trade Name:	Glidesheath Slender™
	Classification Name:	Sheath Introducer
	Premarket Notification:	K142183
	Manufacturer:	Terumo Medical Corporation

Device Description	The 7F PreludeEASE™ Hydrophilic Sheath Introducer consists of a sheath introducer with compatible vessel dilator that snaps securely into the sheath introducer hub. The sheath hub contains an integral hemostasis valve. A rotating suture ring is affixed to the sheath hub. The sheath tubing is coated with a hydrophilic coating. A sidearm is affixed to the sheath hub and has a 3-way stopcock at its proximal end. The 7F PreludeEASE Hydrophilic Sheath Introducer is available in 11cm, 16cm and 23cm lengths and is designed to accept 0.018", 0.021" and 0.035" diameter guide wires. The 7F PreludeEASE™ Hydrophilic Sheath Introducer is marketed with any of the following components, depending on the product configuration: guide wire, metal access needle, access needle with inner metal needle and outer plastic cannula, syringe, scalpel and BowTie™ guide wire insertion device.
Indications for Use	There is no change in the indications for use statement from the predicate to the subject device. The Merit PreludeEASE Hydrophilic Sheath Introducer is intended to provide access and facilitate the percutaneous introduction of various devices into veins and/or arteries, including but not limited to the radial artery, while maintaining hemostasis for a variety of diagnostic and therapeutic procedures. The access needle with inner metal needle and outer plastic cannula is used to gain access to the vein or artery for placement of guide wires.
Comparison to Predicate Device	The technological characteristics of the subject 7F PreludeEASE Hydrophilic Sheath Introducer are substantially equivalent to those of the predicate 4F through 6F PreludeEASE Hydrophilic Sheath Introducer. The subject device has the same basic design as the predicate device in that it consists of sheath tubing, hub, sidearm and stopcock and is provided with a vessel dilator. The difference between the subject and the predicate devices is in the French size to expand the product line to include the 7F sheath introducer. The subject device utilizes the same materials as the predicate device with the exception of the orange colorant which is used to differentiate the 7F size from the other sizes.

Performance Data

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. Performance testing of the subject 7F PreludeEASE Hydrophilic Sheath Introducer was conducted based on the risk analysis and based on the requirements of the following international standard:

- ISO 11070:1998, *Sterile, single-use intravascular catheter introducers*
- ISO 11135:2014*, Sterilization of health care products – Ethylene oxide – Requirements for development, validation and routine control of a sterilization process for medical devices*
- ASTM D4169-09, *Standard Practice for performance Testing of Shipping Containers and Systems*
- ISO 2233:2000, *Packaging – Complete, filled transport packages and unit loads – Conditioning for testing*
- ISO 10993-1:2009, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process*, and FDA guidance *Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices*, May 1, 1995
- ANSI/AAMI/ISO 10993-3:2003, *Biological Evaluation of Medical Devices – Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity*
- ISO 10993-4:2002 (Amd.1:2006)*, Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood*
- ISO 10993-5:2009*, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*
- ISO 10993-7:2008, *Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals*
- ISO 10993-10:2010, *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*
- ISO 10993-11:2006, *Biological evaluation of medical devices – Part 11: Tests for systemic toxicity*
- ASTM F756-08, *Standard practice for assessment of hemolytic properties of materials*
- United States Pharmacopeia 35, National Formulary 30, 2012 <151> Pyrogen Test

The following tests were performed to demonstrate there were no unacceptable risks associated with the changes made to the device:

Performance Testing - Bench

- Size Designation
- Kink Resistance
- Sheath / Dilator Tip Peel Back
- Surface
- Hydrophilic Coating Lubricity

- Hydrophilic Coating Coverage and Adherence
- Hydrophilic Coating Length
- Sheath Stiffness and Flex Modulus
- Sheath Introducer Hub to Tubing Pull (Force at Break)
- Sheath Introducer Tubing Pull (Force at Break)
- Dilator Hub to Tubing Pull (Force at Break)
- Dilator Stiffness and Flex Modulus
- Sheath Introducer Assembly Leak
- Radiodetectabillity
- Simulated Use

Performance Data

Biocompatibility

- Cytotoxicity
- Sensitization
- Intracutaneous Injection
- Acute Systemic Toxicity
- Pyrogenicity
- Genotoxicity
- Hemolysis
- Thrombogenicity
- Complement Activation
- Chemical Characterization

The results of the testing demonstrated that the subject 7F PreludeEASE Hydrophilic Sheath Introducer met the predetermined acceptance criteria applicable to the safety and efficacy of the device.

Summary of Substantial Equivalence

Based on the indications for use, design, safety and performance testing, the subject 7F PreludeEASE Hydrophilic Sheath Introducer meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the PreludeEASE Hydrophilic Sheath Introducer, K140543 manufactured by Merit Medical Systems, Inc..